

Contains No CBI



TOXICOLOGY DEPARTMENT

P.O. BOX 12014, 2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709
(919) 549-2000 TELEFAX (919) 549-8525
INTERNATIONAL TELEX NUMBER 4999378-ANSWERBACK APC RTP

91 OCT 30 AM 8:26

October 29, 1992

A

VIA FEDERAL EXPRESS

8EHQ-92-12499

88920010684

INIT

Document Processing Center (TS-790)
Office of Toxic Substances
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID No.: 8ECAP - 0004

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiary Rhône-Poulenc Ag Company (RPAC), the following information is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA. This information is from one of the twenty studies identified in Attachment 1 of RPI's CAP Agreement with EPA, and thus, no copies of the report are enclosed as per Unit II.A.4 of the CAP Agreement. The information from the subject report was originally submitted to EPA under Section 8(e) on January 15, 1991 (EPA Document Control Number 8EHQ-0191-1162S).

This letter provides information on M&B 46030. Its CAS number and chemical index name are 120068-37-3 and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile. This chemical is manufactured in Europe and imported by RPAC for pesticide research and development.

No claims of confidentiality are made for this submission. Please note that RPAC released previous confidentiality claims for the subject chemical on September 8, 1992. The title of the report is "M&B 46030: Preliminary Study to Assess Effects on Reproductive Performance in Rats". The following is a summary of the adverse effects observed in this study.

This study was submitted under Section 8(e) because the number of implantation sites, litter size, and survival were reduced at the highest dose. Test material was administered in the diet to rats at dose levels of 0, 1, 5, 30, 100, or 500 ppm (six rats/sex/group) for 15 days prior to pairing, and throughout mating, gestation, and lactation to postnatal day 4. One male and one female at 500 ppm died during the first week of treatment.

mm
8/2/95

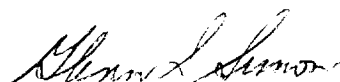
At 500 ppm, decreased numbers of implantations and live births and poor pup survival postpartum were observed. There were two animals in this group with total postnatal litter loss. Pup weight gain to postnatal day 4 was also reduced in the 500 ppm group versus controls. Females and litters in the other treatment groups were unaffected.

This study was previously reported to EPA under Section 8(e) on January 15, 1991 (EPA Document Control Number: 8EHQ-0191-1162 S), and one copy of the report was submitted on August 5, 1991. Six other TSCA Section 8(e) notices were submitted on this chemical. The EPA Document Control Numbers for these submissions are 8EHQ-0391-1199S, 8EHQ-0591-1232S, 8EHQ-0791-1284S, 8EHQ-0791-1285S, 8EHQ-0891-1315S, and 8EHQ-0392-2540S. Also several Section 8(e) notices will be submitted on this compound under the CAP.

In total, RPI is submitting three copies of this cover letter: an original and two copies.

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

A handwritten signature in cursive script, appearing to read "Glenn S. Simon".

Glenn S. Simon, PhD, DABT
Director of Toxicology

Triage of 8(e) Submissions

Date sent to triage: 2/17/96

NON-CAP

CAP

Submission number: 12499A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Gordon Cash (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - HERD (1 copy each)

STOX CTOX EPI RTOX GTOX
STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

- ☒ This is the **original** 8(e) submission; refile after triage evaluation.
- ☐ This **original** submission has been **split**; rejoin after triage evaluation.
- ☐ Other:

Photocopies Needed for Triage Evaluation

entire document: 0 1 2 3

front section and CECATS: 0 1 2 3

Initials: JW

Date: 6/26/96

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:

Submission # 8EHQ-1092-12499 SEQ. ATYPE INT SUPP FLWPSUBMITTER NAME: Rhone-Poulenc
Inc.

INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECH)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

0672 REFER TO CHEMICAL SCREENING0678 CAP NOTICE

VOLUNTARY ACTIONS:

0401 NO ACTION REPORTED

0402 STUDIES PLANNED/IN PROGRESS

0403 NOTIFICATION OF WORK RESUMED

0404 LABEL/MSDS (CHANGES)

0405 PROCESS/HANDLING (CHANGES)

0406 APP/USE DISCONTINUED

0407 PRODUCTION DISCONTINUED

0408 CONFIDENTIAL

SUB. DATE: 10/29/92 OTS DATE: 10/30/92 CSRAD DATE: 08/02/95

CHEMICAL NAME:

1H - pyrazole - 3 - carbonitrile, 5 - amino -
1 - [2,6 - dichloro - 4 - (trifluoromethyl)
phenyl] - 4 - [(trifluoromethyl) sulfinyl] -

CAS#

120068-37-3 → m + B 46030

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
<u>0207</u> REPRO/TERATO (ANIMAL)	<u>01 02 04</u>	0222 EMER INCI OF ENV CONTAM	01 02 04	<u>0247</u> DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	<u>0248</u> PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0239 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA NON-CBI INVENTORY ONGOING REVIEW SPECIES TOXICOLOGICAL CONCERN: USE: PRODUCTION:
 YES YES (DROP/REFER) RAT LOW R & D import
 CAS SR NO NO (CONTINUE) MED pesticide
IN PROGRESS REFER HIGH

Summary only
0191-11625, 0391-11995, 0591-12325, 0791-12845, 0791-12855, 0891-13155, 0392-25405

Preliminary study to assess Repro Performance - Rats
 via diet 6 groups of 6 rats/sex 0, 1, 5, 30, 100, 500 ppm
 15 days prior to mating, mating, gestation, lactation - PND 4.

at 500 ppm - ↓ #'s implantations
 and live births. ↓ pup weight
 gain at PND 4. Poor pup survival